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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,827	03/26/2007	Kazumi Koga	BY0033P	9797
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 09/19/2008		<div>EXAMINER</div> <div>LANDSMAN, ROBERT S</div>	
			<div>ART UNIT</div> <div>1647</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>09/19/2008</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,827

Applicant(s)

KOGA ET AL.

Examiner

ROBERT LANDSMAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 4 and 5 is/are allowed.
- 6) ☒ Claim(s) 3, 6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 8/1/08 has been entered.
- B. Claims 2-6, 8 and 9 are pending and are the subject of this Office Action.

2. Specification

- A. The objection to the specification is withdrawn in view of Applicants' amendment to add a sequence identifier to the Brief Description of Figure 1.

3. Claim Objections

- A. All claim objections have been overcome in view of Applicants' amendments.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claims 3, 6 and 9 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 5/1/08. Applicants have obviated the rejection with regard to hybridization. Furthermore, the Examiner appreciates Applicants' realization that the rejection was intended to cover claim 3, not allowable claim 2.

Claims 3 and 9 recite that the nucleotide sequence is **at least 96% identical** to SEQ ID NO:1. However, the breadth of this claim is excessive since Applicants have not provided a functional limitation which would identify the encoded protein as a simian ORL-1 receptor, or as an ORL-1 receptor in general, such as a step requiring that the encoded protein binds nociceptin. Claim 9 recites, for example, "a step of transferring a simian ORL-1". However, it is not clear what constitutes a simian ORL-1 protein. Applicants have only provided guidance and working examples of the ORL-1 receptor of SEQ ID NO:2. Based on this minimal guidance and working examples, it would be unpredictable to the artisan how to make a functional ORL-1 receptor. For example, it is not taught what residues are critical to retain ORL-1 function.

Claims 6 and 9, however, still read on an in vivo screening method (claim 9) or as it pertains to in vivo gene therapy (claim 6). It is suggested that the term "isolated transformant" or "isolated cell" be used

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to clarify that the method, or cell, is limited to in vitro use. The Examiner was unable to find any reference to in vivo screening or gene therapy; however, if Applicants can confirm that their specification does not contemplate any in vivo screening, or gene therapy, then the rejection will be reconsidered without a claim amendment being necessary.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 2 (intended to be claim 3) and 8 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 3, 5, 8 and 9 under 35 USC 112, second paragraph, regarding “ORL1” has been withdrawn in view of Applicants' amendment to define the term upon first use.

B. Claims 8 and 9 remain rejected under 35 USC 112, second paragraph, with regard to “ORL1 activity” for the reasons already of record on page 6 of the Office Action mailed 5/1/08. Applicants have not amended this term, nor provided any arguments addressing this issue.

C. The rejection of claim 8 under 35 USC 112, second paragraph, regarding “consisting of” has been withdrawn in view of Applicants' amendment to the claim to recite “comprising”.

7. Claim Rejections - 35 USC § 102

A. The rejection of claims 3, 8 and 9 under 35 USC 102 has been withdrawn in view of Applicants' amendments to the claims to recite 96% identical. Evans do not teach a nucleic acid with an overall sequence identity of 96% or greater.

8. Claim Rejections - 35 USC § 103

A. The rejection of claims 3, 8 and 9 under 35 USC 102 has been withdrawn in view of Applicants' amendments to the claims to recite 96% identical. Evans do not teach a nucleic acid with an overall sequence identity of 96% or greater.

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9. Note

A. No rejection of claims 8 and 9 is being made under 35 USC 112, first paragraph, with regard to the phrase "with a substitution of...one, or between 2 and 6 amino acids." The Examiner is interpreting the term "with" as closed language, meaning that the protein can have no more than 6 alterations.

10. Conclusion

A. Claims 2, 4 and 5 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647